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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/726,193	11/29/00	CHENG	X 300.1023

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EXAMINER	
FUBARA, B	
ART UNIT	PAPER NUMBER
1615	5

DATE MAILED: 10/01/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/726,193	CHENG ET AL.	
	Examiner	Art Unit	
	Blessing M. Fubara	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 November 2000* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

1. Claims 1-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Physician Desk Reference (PDR) on GLUCOPHAGE (50th edition, pages 752-757).

The Physician Desk Reference on GLUCOPHAGE teaches metformin hydrochloride tablets that can be administered daily (see pages 752-757, 50th edition). It is inherent that administration of the composition would provide therapeutic plasma levels over a period of time. The claims of the instant invention are very broad. The claims of the instant invention do not recite any particular metformin amounts/concentration in the claimed formulation that would present patently distinctness from the prior art. A mere recitation of what the formulation would do over a period of 24 hours does not distinguish over the prior art since a composition as that recited in the instant claims would inherently provide therapeutic plasma levels in a subject. The mere recitation of when the formulation is administered or that food intake would influence the bioavailability of the drug does not distinguish over a composition claim. The claims are not method or process claims. The teachings of the PDR reference anticipate the claims.

2. Claims 1-29 rejected under 35 U.S.C. 102(e) as being anticipated by Moeckel et al. (US 5,955,106).

Moeckel teaches a composition metformin or pharmaceutically active salt. The composition also comprises cellulose derivatives, dextrins, starch and carbohydrate based

polymer and natural or hydrophylic gum (column 3, lines 20-40). The composition is formulated into a tablet (column 4, lines 51). It is inherent that the composition would provide a therapeutic level of metformin over a period of time when administered to a subject in need thereof. The invention broadly claims a formulation of metformin without any specifics. The discussion above applies to the rejection here how and when a composition is administered is not critical in a composition claim. The recitation that food intake would influence the bioavailability of the drug does not distinguish the composition claims over the prior art. The teaching of Moeckel anticipates the claims as recited.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bhagwat et al. (US 6,056,977).

Bhagwat et al. discloses a controlled release pharmaceutical coated tablet formulation wherein the formulation comprises the hypoglycemic drug, glipizide, surfactants, excipients, diluents, hydroxymethylcellulose, hydroxypropyl methylcellulose phthalate, methacrylic acid ester copolymers, suitable plasticizer, sorbitol, sodium chloride enhancer, ethylenediamine and polyvinylpyrrolidone. See abstract, column 4, lines 27-54, column 6, lines 20-67, column 7, line 66 to column 8 and line 60, column 9, line 63 to column 10 and line 33, column 11, lines 30-41, column 12, lines 22-47, examples 4, 5, 7 and 8 and claims 1-16. The amounts of diluent in the

formulation ranges from 5% to about 50% by weight of the total dosage unit (column 8, line 66). Bhagwat et al. teaches that hypoglycemic drugs such as metformin, buformin, glipizide and phenformin are formulated as controlled release microspheres, and that art known extended release glipizide dosage forms are prepared as osmotic device wherein the core is surrounded by a semipermeable membrane that has laser-drilled orifice (column 3, lines 8-47). The expected result is a controlled release pharmaceutical tablet formulation comprising hypoglycemic agent, semipermeable membrane having an orifice/aperture and surrounding a core, plasticizers, enhancers, diluents, carriers and binders such as polyvinylpyrrolidone. The instant claims are broad and when and how the composition is administered is not critical to a composition claim. The influence of food intake on the bioavailability of the drug is not critical in a composition claim. The claims are directed to a composition comprising antihyperglycemic drug or a pharmaceutically acceptable salt and the agent is metformin. Bhagwat suggests metformin controlled release formulation.

Therefore, it is prima facie obvious to one of ordinary skill in the art at the time the invention was made to use the teachings of Bhagwat et al. One having ordinary skill in the art would have been motivated to prepare a controlled release dosage tablet wherein the dosage tablet comprises glipizide hypoglycemic agent, apertured semipermeable membrane surrounding a core, surfactants, excipients, diluents, hydroxymethylcellulose, hydroxypropyl methylcellulose phthalate, methacrylic acid ester copolymers, suitable plasticizer, sorbitol, sodium chloride enhancer, ethylenediamine and polyvinylpyrrolidone.

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1-29 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-29 and 1-15 of U.S. Patent Nos. 6,099,859 and 5,837,379 respectively. Although the conflicting claims are not identical, they are not patentably distinct from each other because the prior art references teach metformin composition that read on the scope of the invention recited in the instant claims.

7. Claims 1-19 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-54 of copending Application No. 09/594,637. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications teach a composition comprising metformin or pharmaceutically acceptable salt thereof.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Observation/Suggestion

The definitions for T_{max} and C_{max} should be recited at least at the initial occurrence in a claim, with the abbreviation enclosed in parenthesis. The abbreviation may then be

subsequently used if the inventors so desire. Please refer to claims 4, 6,9, 10, 12, 13, 15, 16, 19, 22, 26 and 29. The same observation/suggestion may apply to USP in claims 24 and 27.

Applicants may kindly resubmit the information disclosure statement accompanied if possible with the cited references as the document is not available in the application.

8. Applicants' cooperation is requested in correcting any errors of which applicants may become aware in the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is 703-308-8374. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Blessing Fubara
September 27, 2001

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600